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February 9, 2006

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Andrew C. von Eschenbach, M.D.  
Acting Commissioner  
Food and Drug Administration  
5600 Fisher Lane, Room 1555  
Rockville, Maryland 20857

Dear Dr. von Eschenbach:

We understand that a series of related decisions by the Center for Food Safety and Applied Nutrition (CFSAN) apparently permits the use of carbon monoxide to alter the color of meat and fish to make those substances appear edible beyond the time when they may decompose sufficiently to be contaminated by one or more dangerous toxins.

A review of Food and Drug Administration (FDA) responses to GRAS (generally recognized as safe) notices by interested companies indicates that the FDA has apparently decided that (1) it can ignore its own regulations, (2) that it can issue potentially dangerous determinations without public hearings or any form of notice and comment procedure, and (3) that it will accede to the requests of meat and fish packers and packaging manufacturers seeking to extend the shelf life appeal of meat and fish regardless of a potential impact on the public health.

Our review of the very limited public documents and other materials (obtained by interested parties under the Freedom of Information Act (FOIA) and provided to us) raises serious questions that require your prompt attention:

1. What is the reason to believe that this artificial coloration of meat and fish will not fool consumers to their detriment? The data attached to GRN 000083 ("Pactiv" notification) and GRN 000143 ("Precept Foods" notification) reveal no arguments, much less definitive science, to suggest that consumers will not be fooled by artificial coloring of meat products. In fact, that is the stated purpose of their petitions. The FDA response to GRN 000167 (Tyson notification) suggests that CFSAN reviewed no data in that case that would show that consumers can distinguish meat colored to look fresh but of potentially dangerous age from meat that is in fact fresh.

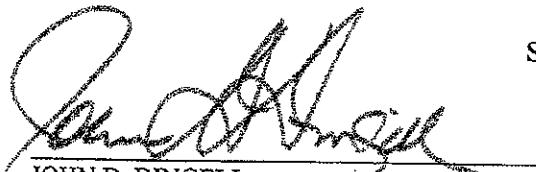
2. The Precept Foods notice argues that end dating will be sufficient notice to consumers of meat in danger of spoiling. None of the documents obtained under FOIA associated with that notice, however, purport to have measured the extent to which consumers are guided by end dating when purchasing meat, a commodity that has typically been purchased based on appearance. Nor is there any indication in the FDA response to any of the notices of an FDA requirement regarding the type, size, color, or placement of "use or freeze by" information on the package. Does the FDA possess and did it consider scientific studies on how consumers distinguish good meat from that which is going bad? If not, why not? Does the FDA have requirements that specify how prominent critical safety information such as the end date must be displayed on packaged meat and fish? If not, why not?
3. Your CFSAN scientists apparently think there is no danger to the public health in permitting the packagers to disguise the degradation of meat and fish. What is the basis for that belief? Please provide all relevant documentation including all internal notes or other memorandum where the issue of disguising the appearance of meat and fish was considered.
4. A plain reading of 21 CFR 173.350(c) appears to categorically prohibit the use of carbon monoxide on "fresh meat products." Is this prohibition no longer operative? Please explain whether the FDA now disagrees with its own regulation and, if so, why it has not addressed the matter through notice and comment rulemaking.
5. Given that the European Union has banned the use of carbon monoxide on meat and fish products, why does the FDA maintain that such use is "generally recognized as safe"?
6. In a Citizen's petition filed November 15, 2005, Kalsec argues that neither FDA nor the Food Safety and Inspection Service (FSIS) has ever before approved a color additive for meat precisely because it promotes deception by making meat appear fresher than it is, thus violating Section 721 (b)(6) of the Act and 21 CFR 379e (b)(6). What is the basis for CFSAN's disregard of both the statutory and regulatory prohibition of disguising meat by artificial coloration with carbon monoxide?
7. Please provide all documents including notes and memoranda relating to all contacts with FSIS personnel regarding GRN000143.
8. The use of carbon monoxide on fish is discussed in GRN 000015. Carbon monoxide is used as an ingredient in "tasteless smoke" which has alleged preservative properties for treating tuna before freezing and thus is not purely employed for its ability to disguise degradation. But the potential for such disguised spoilage in a food that is often eaten raw is of concern. What steps has the FDA taken to assure that fish sellers have not relied on its GRAS notice responses to treat packaged fish with carbon monoxide to make it appear to be fresher than it is?

Dr. Andrew von Eschenbach  
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9. Should the FDA require that the presence and purpose of carbon monoxide be prominently labeled so consumers can be aware of what they are buying?

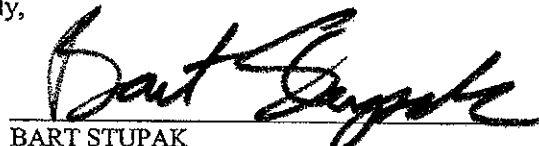
FDA is first and foremost charged by Congress with protecting the public health and the safety of the food supply. But the FDA's decisions to not object to GRAS notices regarding the use of carbon monoxide on meat or fish products ignore those mandates. Given the lack of discernible consumer benefit and the obvious increase in risk to consumers of meat and fish from these decisions, we request that you withdraw the FDA response to GRAS notices GRN 000167, GRN 000143, and GRN 000083. And if the FDA believes that it can demonstrate a favorable risk/benefit ratio on the question of the application of carbon monoxide to color fresh meat and/or fish, then the FDA should go to notice and comment rulemaking to acquire the authority to permit such usage.

Thank you for your attention to this public health matter and to our concerns. With regard to questions and related document requests made in this letter, we would appreciate your responses no later than the close of business, Thursday, February 23, 2006. If you have any questions regarding this request, please have your staff contact David Nelson, Minority Investigator/Economist with the Committee on Energy and Commerce, at (202) 226-3400.



JOHN D. DINGELL  
RANKING MEMBER

Sincerely,



BART STUPAK  
RANKING MEMBER  
SUBCOMMITTEE ON OVERSIGHT  
AND INVESTIGATIONS

CC: The Honorable Joe Barton, Chairman  
Committee on Energy and Commerce

The Honorable Ed Whitfield, Chairman  
Subcommittee on Oversight and Investigations

Dr. Richard Raymond, Under Secretary for Food Safety  
Department of Agriculture